

## **REMARKS**

### **I. Claim Status**

Reconsideration of the present application is respectfully requested. Claims 1-9, 11-13, 15, 17, 31 and 32 are pending. Claims 10, 14, 16 and 18-30 are cancelled without prejudice. Claims 1 and 11 have been amended to more clearly describe the claimed invention. The claim amendments are supported by the specification and claims as originally filed, for example, at pages 47-52, and claim 11. No new matter has been added to the claims by these amendments. Applicants thank the Examiner for withdrawing the objection to claim 1.

### **II. Rejections Under 35 U.S.C. § 103(a)**

- A. U.S. Patent No. 5,985,918 to Modak et al. and U.S. Patent No. 6,344,218 to Dodd et al. in view of U.S. Patent No. 5,902,572 to Luebbe et al.

Claims 1-4, 6-8, 11-13, 15, 17, 31 and 32 stand rejected as unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,985,918 (to Modak et al.), and U.S. Patent No. 6,344,218 (to Dodd et al.), in view of U.S. Patent No. 5,902,572 (to Luebbe et al.). The Examiner contends that Modak describes topical formulations comprising water, emollients, excipients and organic salts of zinc in a concentration of between 0.1-15%. The Examiner further alleges that Dodd describes an aqueous deodorizing composition comprising an alcohol, a water-soluble metallic zinc salt, a thickener, an emollient, water, surfactants, and antimicrobial agents such as benzalkonium chloride, chlorhexidine and mixtures thereof. The Examiner states that Luebbe describes gel deodorant compositions comprising zinc salts and farnesol. According to the Examiner, it would have been obvious for an artisan of ordinary skill to combine the zinc composition of Modak with the antimicrobial composition of Dodd and the farnesol of Luebbe to form the anti-irritant composition described by the pending claims, thus rendering the claims obvious. Furthermore, the Examiner alleges that Applicants' assertion that practicing the claimed invention produces surprising and unexpected results is not persuasive with regard to the nonobviousness of the claims. In particular, the Examiner is not persuaded by the assertion that the low zinc salt concentrations encompassed by the present claims, in contrast to compositions comprising high concentrations of zinc salts, can reduce irritation without decreasing the antimicrobial activity of agents present in the same zinc salt composition, is an unexpected result. According to the Examiner, because the application provides no comparison between

antimicrobial compositions comprising high and low zinc salt concentrations, such an assertion is not persuasive.

Applicants respectfully traverse the rejection and submit that the present claims are not obvious over the cited art. First, to support an assertion of obviousness, the Examiner must show that “all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art.” M.P.E.P. § 2143.02. *See also KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S. 2007), 82 USPQ2d at 1395.

Applicants submit that claim 1 as amended recites an anti-irritant composition which comprises 0.05% - 4% (weight/weight) incroquat. None of Modak, Dodd or Luebbe discloses a composition comprising incroquat. As such, the combined teaching of the three references does not render the claims obvious because the composition defined by the three references does not describe all the elements of the claimed invention.

Second, Applicants submit that the claims as amended are not obvious in view of the cited references because the claimed invention represents a surprising and unexpected result in view of the prior art. *See* M.P.E.P. § 716.02(a) and § 2143.02; *see also In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963). As previously discussed in the responses filed October 15, 2007 and April 28, 2008, the addition of zinc salts at low concentrations to the claimed composition was able to produce an anti-irritant effect without reducing the effectiveness of antimicrobial agents present in the same composition (*see, e.g.*, Example 4 at pages 33-36; Example 5 at pages 36-37; and Example 13 at pages 55-60). The reduction in irritation achieved by the low concentration zinc salts encompassed by the claimed invention represents a surprising and unexpected result in view of the prior art, regardless of whether or not an antimicrobial agent is present in the same composition as the zinc salts. For at least this reason, the claims are not obvious over the cited references.

Examples 2 and 7 of the specification (*see* pages 29-31 and 43-44) further support this surprising anti-irritant capacity achieved by the claimed composition. As shown in these examples, compositions comprising two or more zinc salts at low concentrations (*i.e.*, between 0.1 and 1%; and between 0.1 and 2%, respectively), were able to reduce irritation caused by a skin irritant (*i.e.*, methyl salicylate, *see* Example 2), or by latex-induced contact dermatitis (*see* Example 7). Furthermore, these reductions in irritation were achieved both in the presence (*see* Example 2) and absence (*see* Example 7) of an antimicrobial agent. Such results are in contrast

to the teaching of the prior art, as evidenced by Modak, which discloses that high concentrations of zinc salts are required to reduce irritation. Specifically, Modak discloses that compositions comprising zinc salts were only able to eliminate latex-induced irritation when the salts were present at high concentrations of at least 2.5%. Furthermore, only one zinc salt, zinc stearate, was an effective anti-irritant at a concentration of 2.5%; every other zinc salt tested required a concentration of at least 4% to reduce irritation. *See* Modak, col. 3, Table A. In contrast, as disclosed in Example 7 of the instant application (*see* page 43 and 44), a composition comprising four zinc salts at concentrations of 0.5%, 0.1%, 0.1% and 2.0% was able to eliminate latex-induced irritation in a treated patient.

According to the Examiner, Modak suggests that zinc salts may be present in a topical formulation in a range of from 1 to 15%, and further, that one embodiment discloses a range of from 0.1 to 1% zinc salicylate. *See* page 5 of the July 24, 2008 Office Action; and Modak at col. 2, lines 27-35. The claimed invention recites a composition comprising two or more water-soluble organic salts of zinc, wherein said water-soluble organic salts of zinc are at concentrations of between 0.1% and 2%. Applicants submit that Modak discloses that formulations comprising two or more zinc salts that are effective anti-irritants comprise at least one zinc salt at a concentration of 3% or greater. *See* Modak, col. 2, lines 55-67. Furthermore, in formulations comprising zinc salicylate at a concentration of 1% or less, Modak describes the presence of one or more additional zinc salts in the same formulation at concentrations of 3, 4 or 5%. *See* Modak, col. 2, lines 61-65. Thus, although Modak discloses that zinc salicylate may be present in a composition at a concentration of between 0.1 and 1%, for the composition to be an effective anti-irritant, other zinc salts must be present in the same composition at higher concentrations of at least 3%. As such, the reduction in irritation achieved by the low concentrations of zinc salts encompassed by the claimed invention represents an unexpected and surprising result in view of the prior art, which is indicative of the claims' nonobviousness.

Applicants further submit that neither Dodd nor Luebbe disclose that adding zinc salts to a composition at low concentrations is effective to prevent irritation. Dodd includes zinc salts, along with antimicrobials such as chlorhexidine salts, benzalkonium chloride, and mixtures thereof, in a deodorant composition as odor control agents, but is silent with regard to the effect of low zinc salt concentrations on irritation. *See* Dodd, col. 5, lines 60-67; and col. 8, lines 8-27. Additionally, unlike the claimed invention, Dodd's failure to recognize the advantage of low zinc salt concentrations is further evidenced by its disclosure that zinc concentrations as high as 10% may be used in the disclosed compositions. *See* Dodd, col. 6, lines 17-19.

Similar to Modak and Dodd, Applicants also submit that Luebbe fails to recognize that low concentrations of zinc salts can reduce irritation. Luebbe discloses that farnesol and zinc salts are two of among many different agents that are useful as antimicrobial “deodorant actives,” which are effective in preventing or eliminating malodor associated with perspiration when present in a deodorant formulation at a concentration of 0.001-50% by weight. *See* Luebbe col. 1, lines 58-60; and col. 3, lines 2-21. Like Dodd, Luebbe is silent with regard to the effect of low concentration zinc salts on irritation. Thus, although the combined teaching of the cited references may at best describe a composition comprising zinc salts, the zinc salts, in view of Modak, would need to be present at concentrations above those recited by the pending claims to achieve an anti-irritant effect. As such, a skilled artisan would not have expected to achieve the surprising and unobvious results of the present invention by combining the teachings of the cited references.

Applicants further assert that the nonobviousness of the claims is supported by the synergistic antimicrobial effect achieved by the claimed anti-irritant composition. As described in Example 10 of the application (*see* pages 47-52), the combination of chlorhexidine gluconate, benzalkonium chloride and incroquat in a single composition resulted in an antimicrobial effect that was greater than the expected additive effect of three compounds. Specifically, a composition comprising chlorhexidine gluconate and benzalkonium chloride exhibited a ten-fold reduction in recovered bacteria compared to a control composition, while a composition containing incroquat only exhibited a 0.48 fold reduction in bacteria compared to control. When the three agents were combined together in a single composition, a 4-log reduction in bacteria was achieved compared to the control composition. *See* the specification at page 48, paragraph 93; page 48, Table 10; and page 49, Table 11. Furthermore, adding low concentrations of zinc salts to the composition comprising the three agents did not reduce the antimicrobial effectiveness of the composition. *See* page 50, Table 12.

Thus, in view of the cited references failure to describe all the elements of the claimed invention, in addition to the unexpected reduction of irritation and synergistic antimicrobial effect achieved by the claimed invention, Applicants respectfully request that the rejection be withdrawn.

- B. U.S. Patent No. 5,985,918 to Modak et al., U.S. Patent No. 6,344,218 to Dodd et al. and U.S. Patent No. 5,902,572 to Luebbe et al. in view of U.S. Patent No. 4,868,169 to O’Laughlin et al. or U.S. Patent No. 5,073,372 to Turner et al.

The Examiner has maintained the rejection of claim 5 under 35 U.S.C. § 103(a) as obvious over Modak, Dodd and Luebbe in view of U.S. Patent No. 4,868,169 (to O’Laughlin et al.). The Examiner has also maintained the rejection of claim 9 under 35 U.S.C. § 103(a) as obvious over Modak, Dodd and Luebbe in view of U.S. Patent No. 5,073,372 (to Turner et al.). As described above, the Examiner contends that Modak, Dodd and Luebbe disclose an anti-irritant composition comprising organic salts of zinc, an antimicrobial compound and farnesol. The Examiner further alleges that O’Laughlin describes creams which comprise the skin conditioner Glucam P-20, and that Turner describes facial emulsion formulations comprising organopolysiloxanes, including dimethiconol fluid in dimethicone. According to the Examiner, it would have been obvious to combine the skin conditioning agents and excipients of O’Laughlin and Turner with the anti-irritant compositions of Modak, Dodd and Luebbe.

Applicants respectfully disagree. As previously discussed, formulating a composition with low concentrations of zinc salts and antimicrobial agents, as recited by the pending claims, provides for an unexpected and surprising reduction in irritation, as well as a synergistic antimicrobial effect. The combined teaching of Modak, Dodd and Luebbe does not suggest or describe that adding zinc salts to a composition at such low concentrations can effectively reduce irritation, nor do the references suggest a combination of agents which can achieve antimicrobial synergy.

Applicants further submit that O’Laughlin is directed to oil-in-water steroidal cream formulations which are stable and do not undergo syneresis. *See* O’Laughlin, col. 22, lines 9-15. Turner discloses that adding dimethiconol fluid in dimethicone to facial formulations prevents the appearance of oily skin by controlling the distribution of sebum (skin oil) across the face. *See* Turner, col. 6, lines 33-56. Neither O’Laughlin nor Turner provide any disclosure or suggestion that low concentrations of zinc salts can reduce irritation, and both references are silent with regard to synergistic combinations of antimicrobial agents. As such, combining either O’Laughlin or Turner’s ingredients with the composition defined by Modak, Dodd and Luebbe does not rescue the three references’ failure to describe a synergistic antimicrobial composition that can achieve a reduction in irritation with low concentrations of zinc salts. Further, Applicants note that neither O’Laughlin nor Turner disclose a composition comprising incroquat,

and as such, the combined teaching of the five references fails to describe all the elements of the claimed invention. Thus, for the foregoing reasons, Applicants assert that the claims as amended are not obvious over the cited references, and respectfully request that the rejections be withdrawn.

### **III. Double Patenting**

The Examiner has rejected claims 1-9, 11-13, 15, 17, 31 and 32 on the grounds of nonstatutory obviousness-type double patenting over claims 1, 4-8, and 11-15 of U.S. Patent No. 5,965,610 to Modak et al. (“the ‘610 patent”). According to the Examiner, although the conflicting claims are not identical, they are not patentably distinct from each other because the “comprising” language of the ‘610 patent claims allows for the presence of other agents, including the antimicrobials and silicone polymers recited in the instant claims, and further because the instantly claimed concentrations are encompassed by the ‘610 patent claims.

The Examiner has rejected claims 1, 3-9, 11-13, 15, 17, 31 and 32 on the grounds of nonstatutory obviousness-type double patenting over claims 1-3 of U.S. Patent No. 5,985,918 to Modak et al. (“the ‘918 patent”). According to the Examiner, the ‘918 patent claims a composition comprising zinc stearate and zinc salicylate in a “topical cream base.” Although the conflicting claims are not identical, they are not patentably distinct from each other because, as contended by the Examiner, the “comprising” language of the ‘918 patent claims allows for the presence of other agents, including the thickeners, emollients, antimicrobials and silicone polymers recited in the instant claims.

Applicants respectfully submit that the appropriate action will be taken as the Examiner indicates allowable subject matter with regard to the previously discussed rejections under 35 U.S.C. § 103(a).

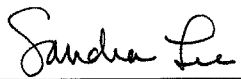
The Examiner has maintained the rejection of claims 1-2 on the grounds of nonstatutory obviousness-type double patenting over claims 14-19 and 39-42 of copending Application No. 10/892,034. According to the Examiner, although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass compositions comprising two or more organic zinc salts. Because the allegedly overlapping claims have not yet been patented, this rejection is provisional. To the extent that claim scope overlaps in any patented case, Applicants respectfully submit that the appropriate action will be taken as the Examiner indicates allowable subject matter with regard to the previously discussed rejections under 35 U.S.C. § 103(a).

#### IV. Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be allowed and passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe that no fee is due at this time. However, if any fees are required, the Commissioner is authorized to charge such fee to Deposit Account No. 02-4377.

Respectfully submitted,  
BAKER BOTTS L.L.P.

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